Amendment No. 1 to HB0837

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Hargrove
Signature of Sponsor

AMEND Senate Bill No. 1706 House Bill No. 837*

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Title 56, Chapter 7, Part 23, is amended by adding the following as a new section:

56-7-2365.

(a) For purposes of this section:

(1) "Health benefit plan" means any hospital or medical expense policy, health, hospital or medical service corporation contract, a policy or agreement entered into by a health insurer or health maintenance organization contract offered by an employer but does not include policies or certificates covering only accident, credit, dental, disability income, long term care, hospital indemnity, Medicare supplement as defined in the Social Security Act, Section 1882(g)(1) specified disease, vision care, other limited benefit health insurance, coverage issued as a supplement to liability insurance, worker's compensation insurance, automobile medical payment insurance or insurance which is statutorily required to be contained in any liability insurance policy or equivalent self insurance.

(2) "Health insurer" means any entity offering a health benefit plan as defined in subdivision (1);

(3) "Routine patient care costs" means the costs associated with the provision of health care services, including drugs, medical devices, and services that would otherwise be covered under the plan or contract if those drugs, medical devices, and services were not provided in connection with an approved clinical trial program, including:

(A) Health care services typically provided absent a clinical trial;

(B) Health care services required solely for the provision of the drug, medical device or service;

(C) Health care services required for the clinically appropriate monitoring of the drug, medical device, or service;

(D) Health care services provided for the prevention of complication arising from the provision of the drug, medical device, or service; and

(E) Health care services needed for the reasonable and necessary care arising from the provision of the drug, medical device, or service, including the diagnosis or treatment of the complications.

(b) The subject of the trial must evaluate a drug, medical device or service that falls within a Medicare benefit category and is not statutorily excluded from coverage. For purposes of this section, "routine patient care costs" does not include the costs associated with the provision of any of the following:

(A) Drugs, medical devices, and services that have not been approved by the federal food and drug administration and that are associated with the clinical trial;

(B) Services other than health care services. such as travel, housing, companion expenses, and other non clinical expenses, that an enrollee may require as a result of the treatment being provided for purposes of the clinical trial;

(C) Drugs, medical devices, and services that are provided solely to satisfy data collection and analysis needs and that is not used in the clinical management of the patient;

(D) Health care services that, except for the fact that they are being provided in a clinical trial, are otherwise specifically excluded from coverage under the enrollee's health plan;

(E) Health care services customarily provided by the research sponsors free of charge for any enrollee in the trial; or

(F) Drugs, medical devices, and services provided solely to determine trial eligibility.

(c) For an enrollee diagnosed with cancer and accepted into a phase I, phase II, phase III, or phase IV clinical trial for cancer, every health benefit plan that is issued, amended, delivered, or renewed in this state, shall provide coverage for all routine patient care costs related to the clinical trials if the enrollee's treating physician, who is providing covered health care services to the enrollee under the enrollee's health benefit plan contract, recommends participation in the clinical trial after determining that participation in the clinical trial has a meaningful potential benefit to the enrollee. For purposes of this section, the clinical trial's endpoints shall not be defined exclusively to test toxicity, but shall have a therapeutic intent.

(d) The treatment shall be provided in a clinical trial that either:

(1) Involves a drug that is exempt under federal regulations from new drug application; or

(2) Is approved by one of the following:

(A) One of the national institutes of health;

(B) The federal food and drug administration, in the form of an investigational new drug application;

(C) The United States department of defense; or

(D) The United States veteran's administration.

(e) In the case of health care services provided by a participating provider, the payment rate shall be at the network negotiated rate based on the member's plan design. In the case of a non-participating provider, the payment shall be at the rate that the member's plan would otherwise pay to a non-

participating provider for the same services, less any applicable co-payments and deductibles.

(f) The provision of services when required by this section shall not, in itself, give rise to liability on the part of the health care service plan.

(g) Nothing in this section shall be construed to limit, prohibit, or modify an enrollee's right to the independent review process available or to the independent medical review system.

(h) Nothing in this section shall be construed to otherwise limit or modify any existing requirements under the provisions of this chapter or to prevent application of co-payment or deductible provision in a plan.

(i) Co-payments and deductibles applied to services delivered in a clinical trial shall be the same as those applied to the same services if not delivered in a clinical trial.

(j) This section shall not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance, except that for specified disease and hospital indemnity insurance, coverage for benefits under this section shall apply, but only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy. Nothing in this section shall be construed as imposing a new benefit mandate on specified disease or hospital indemnity insurance.

(k) Nothing in this section shall be construed to require payment of costs associated with clinical trials that are not routine patient care costs and that would not otherwise be covered by the health benefit plan, including but not limited to costs for services incurred that are related to or the result of the clinical trial.

(l) This section does not require the payment of any patient care costs, routine or otherwise, that are billed by the provider to conduct the clinical trial.

(m) Any entity seeking payment under this section must, at the time payment is sought, notify the health insurer in writing that the patient receiving the services for which payment is sought is the subject of a clinical trial. Such notification shall include the patient's health insurance membership identification number. Failure to comply with this provision by the provider conducting the clinical trial shall relieve the health benefit plan and its enrollee from any obligation to reimburse the provider.

(n) Notwithstanding any provision of law to the contrary, any entity associated with the provision of medical services as a part of a clinical trial pursuant to this part shall, upon receipt of applicable payment by the health benefit plan, hold harmless and relieve the enrollee involved from any liability for services rendered by such provider except for applicable co-payment or co-insurance.

SECTION 2. This act shall take effect July 1, 2005, the public welfare requiring it. This act shall apply to contracts entered into or renewed on and after July 1, 2005.